

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method of administering atropine to a mammal comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition to provide transmucosal absorption of a pharmacologically effective amount of atropine through the oral mucosa of the mammal to the systemic circulatory system of the mammal, the composition comprising: atropine or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and a polar solvent in an amount between 30 and 99.69 percent by weight of the total composition, wherein a therapeutically effective amount of atropine is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

2. (Previously presented) The method of claim 1, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

3. (Previously presented) The method of claim 2, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the atropine or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

4. (Previously presented) The method of claim 3, wherein the polar solvent is present in an amount between 60.9 and 97.06 percent by weight of the total composition, the atropine or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

5. (Previously presented) The method of claim 1, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C₂ to C₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration.

6. (Previously presented) The method of claim 1, wherein the polar solvent comprises polyethylene glycol.

7. (Previously presented) The method of claim 1, wherein the polar solvent comprises ethanol.

8. (Previously presented) The method of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

9. (Canceled).

10. (Previously presented) The method of claim 1, wherein the amount of the spray is predetermined.

Claims 11-21 (Canceled).

22. (Currently amended) A method of administering atropine to a mammal comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition to provide transmucosal absorption of a pharmacologically effective amount of atropine through the oral mucosa of the mammal to the systemic circulatory system of the mammal, the composition comprising: atropine or a pharmaceutically acceptable salt thereof in an amount between 0.005 and 55 percent by weight of the total composition; and a non-polar solvent in an amount between 30 and 99.69 percent by weight of the total composition, wherein a therapeutically effective amount of atropine is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

23. (Previously presented) The method of claim 22, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10 percent by weight of the total composition.

24. (Previously presented) The method of claim 23, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

25. (Previously presented) The method of claim 22, wherein the solvent is selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydrocarbons of linear or branched configuration, C₂-C₆ alkanoyl esters, and triglycerides of C₂-C₆ carboxylic acids.

26. (Previously presented) The method of claim 25, wherein the solvent is a triglyceride.

27. (Canceled).

28. (Previously presented) The method of claim 22, wherein the amount of the spray is predetermined.

Claims 29-39 (Canceled)

40. (Withdrawn and currently amended) A method of administering atropine to a mammal comprising spraying the oral mucosa of the mammal with a buccal spray composition to provide transmucosal absorption of a pharmacologically effective amount of atropine through the oral mucosa of the mammal to the systemic circulatory system of the mammal, the composition comprising: atropine or a pharmaceutically acceptable salt thereof in an amount between 0.2 and 10 percent by weight of the total composition; and a polar solvent comprising propylene glycol and ethanol in an amount between 50 and 99 percent by weight of the total composition, wherein a therapeutically effective amount of atropine is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

41. (Withdrawn) The method of claim 1, further comprising blocking the effects of acetylcholine at muscarine receptors in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

42. (Withdrawn) The method of claim 1, further comprising treating an ulcer in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

43. (Withdrawn) The method of claim 1, further comprising treating a disorder resulting from excessive smooth muscle contraction in the gastrointestinal tract in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

44. (Withdrawn) The method of claim 1, further comprising treating irritable-bowel syndrome in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

45. (Withdrawn) The method of claim 1, further comprising treating intestinal hypermotility and increased frequency of stools associated with administration of an antihypertensive agent in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

46. (Withdrawn) The method of claim 1, further comprising treating diarrhea associated with mild dysentery or diverticulitis in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

47. (Withdrawn) The method of claim 1, further comprising reducing excessive salivation in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

48. (Withdrawn) The method of claim 47, wherein the excessive salivation is caused by heavy metal poisoning.

49. (Withdrawn) The method of claim 48, wherein the excessive salivation is caused by parkinsonism.

50. (Withdrawn) The method of claim 1, further comprising reducing secretions in the upper and lower respiratory tract of a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

51. (Withdrawn) The method of claim 50, wherein the secretions in the upper and lower respiratory tract are caused by acute rhinitis.

52. (Withdrawn) The method of claim 1, further comprising treating parkinsonism in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

53. (Withdrawn) The method of claim 1, further comprising treating cardiovascular collapse resulting from the administration of a choline ester or an inhibitor of cholinesterase in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

54. (Withdrawn) The method of claim 1, further comprising antagonizing vagal cardiac slowing in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

55. (Withdrawn) The method of claim 1, further comprising treating acute myocardial infarction where excessive vagal tone causes sinus or nodal bradycardia or atrioventricular block in a patient comprising spraying the oral mucosa of the patient with the buccal spray composition.

56. (Withdrawn) The method of claim 1, further comprising administering anesthesia to a patient comprising pre-medicating the patient with atropine prior to administering the anesthesia by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

57. (Withdrawn) The method of claim 56, wherein the anesthetics, is selected from the group consisting of halothane, suxamethonium, and neostigmine.

58. (Previously presented) The method of claim 1, further comprising relaxing muscles in the gastrointestinal tract of a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

59. (Withdrawn) The method of claim 1, further comprising treating renal colic in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

60. (Withdrawn) The method of claim 59, further comprising administering an opioid to the patient.

61. (Withdrawn) The method of claim 1, further comprising treating intoxication from exposure to an anticholinesterase agent in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

62. (Withdrawn) The method of claim 61, wherein the anticholinesterase agent is a nerve gas.

Claims 63-84 (Canceled).

85. (Withdrawn) The method of claim 1, further comprising blocking the effects of acetylcholine at muscarine receptors in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

86. (Withdrawn) The method of claim 22, further comprising treating an ulcer in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

87. (Withdrawn) The method of claim 22, further comprising treating a disorder resulting from excessive smooth muscle contraction in the gastrointestinal tract in a patient comprising

spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

88. (Withdrawn) The method of claim 22, further comprising treating irritable-bowel syndrome in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

89. (Withdrawn) The method of claim 22, further comprising treating intestinal hypermotility and increased frequency of stools associated with administration of an antihypertensive agent in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

90. (Withdrawn) The method of claim 22, further comprising treating diarrhea associated with mild dysentery or diverticulitis in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

91. (Withdrawn) The method of claim 22, further comprising reducing excessive salivation in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

92. (Withdrawn) The method of claim 91, wherein the excessive salivation is caused by heavy metal poisoning.

93. (Withdrawn) The method of claim 91, wherein the excessive salivation is caused by parkinsonism.

94. (Withdrawn) The method of claim 22, further comprising reducing secretions in the upper and lower respiratory tract of a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

95. (Withdrawn) The method of claim 94, wherein the secretions in the upper and lower respiratory tract are caused by acute rhinitis.

96. (Withdrawn) The method of claim 22, further comprising treating parkinsonism in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

97. (Withdrawn) The method of claim 22, further comprising treating cardiovascular collapse resulting from the administration of a choline ester or an inhibitor of cholinesterase in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

98. (Withdrawn) The method of claim 22, further comprising antagonizing vagal cardiac slowing in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

99. (Withdrawn) The method of claim 22, further comprising treating acute myocardial infarction where excessive vagal tone causes sinus or nodal bradycardia or atrioventricular block in a patient comprising spraying the oral mucosa of the patient with the buccal spray composition.

100. (Withdrawn) The method of claim 22, further comprising administering anesthesia to a patient comprising pre-medicating the patient with atropine prior to administering the anesthesia by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

101. (Withdrawn) The method of claim 100, wherein the anesthetics, is selected from the group consisting of halothane, suxamethonium, and neostigmine.

102. (Previously presented) The method of claim 22, further comprising relaxing muscles in the gastrointestinal tract of a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

103. (Withdrawn) The method of claim 22, further comprising treating renal colic in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

104. (Withdrawn) The method of claim 103, further comprising administering an opioid to the patient.

105. (Withdrawn) The method of claim 22, further comprising treating intoxication from exposure to an anticholinesterase agent in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

106. (Withdrawn) The method of claim 105, wherein the anticholinesterase agent is a nerve gas.

Claims 107-128 (Canceled).

129. (Currently amended) A method of administering atropine to a mammal comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition to provide transmucosal absorption of a pharmacologically effective amount of atropine through the oral mucosa of the mammal to the systemic circulatory system of the mammal, the composition comprising: atropine or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and a mixture of a polar solvent and a non-polar solvent in an amount of between 30 and 99.69 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1, wherein a therapeutically effective amount of atropine is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system.

130. (Previously presented) The method of claim 129, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.

131. (Previously presented) The method of claim 130, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the atropine or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by

weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.

132. (Previously presented) The method of claim 131, wherein the polar solvent is present in an amount between 60.9 and 97.06 percent by weight of the total composition, the atropine or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

133. (Previously presented) The method of claim 129, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C₂ to C₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration and the non-polar solvent is selected from the group consisting of (C₂-C₂₄) fatty acid (C₂-C₆) esters, C₇-C₁₈ hydrocarbons of linear or branched configuration, C₂-C₆ alkanoyl esters, and triglycerides of C₂-C₆ carboxylic acids.

134. (Previously presented) The method of claim 130, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

134. (Canceled).

136. (Previously presented) The method of claim 129, wherein the amount of the spray is predetermined.

Claims 137-144 (Canceled).

145. (Withdrawn) The method of claim 1, further comprising blocking the effects of acetylcholine at muscarine receptors in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

146. (Withdrawn) The method of claim 1, further comprising treating an ulcer in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

147. (Withdrawn) The method of claim 1, further comprising treating a disorder resulting from excessive smooth muscle contraction in the gastrointestinal tract in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

148. (Withdrawn) The method of claim 1, further comprising treating irritable-bowel syndrome in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

149. (Withdrawn) The method of claim 1, further comprising treating intestinal hypermotility and increased frequency of stools associated with administration of an antihypertensive agent in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

150. (Withdrawn) The method of claim 1, further comprising treating diarrhea associated with mild dysentery or diverticulitis in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

151. (Withdrawn) The method of claim 1, further comprising reducing excessive salivation in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

152. (Withdrawn) The method of claim 151, wherein the excessive salivation is caused by heavy metal poisoning.

153. (Withdrawn) The method of claim 151, wherein the excessive salivation is caused by parkinsonism.

154. (Withdrawn) The method of claim 1, further comprising reducing secretions in the upper and lower respiratory tract of a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

155. (Withdrawn) The method of claim 154, wherein the secretions in the upper and lower respiratory tract are caused by acute rhinitis.

156. (Withdrawn) The method of claim 1, further comprising treating parkinsonism in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

157. (Withdrawn) The method of claim 1, further comprising treating cardiovascular collapse resulting from the administration of a choline ester or an inhibitor of cholinesterase in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

158. (Withdrawn) The method of claim 1, further comprising antagonizing vagal cardiac slowing in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

159. (Withdrawn) The method of claim 1, further comprising treating acute myocardial infarction where excessive vagal tone causes sinus or nodal bradycardia or atrioventricular block in a patient comprising spraying the oral mucosa of the patient with the buccal spray composition.

160. (Withdrawn) The method of claim 1, further comprising administering anesthesia to a patient comprising pre-medicating the patient with atropine prior to administering the anesthesia by spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

161. (Withdrawn) The method of claim 160, wherein the anesthetics, is selected from the group consisting of halothane, suxamethonium, and neostigmine.

162. (Previously presented) The method of claim 1, further comprising relaxing muscles in the gastrointestinal tract of a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

163. (Withdrawn) The method of claim 1, further comprising treating renal colic in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

164. (Withdrawn) The method of claim 163, further comprising administering an opioid to the patient.

165. (Withdrawn) The method of claim 1, further comprising treating intoxication from exposure to an anticholinesterase agent in a patient comprising spraying the oral mucosa of the patient with a therapeutically effective amount of the buccal spray composition.

166. (Withdrawn) The method of claim 165, wherein the anticholinesterase agent is a nerve gas.

Claims 167-188 (Canceled).